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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/628,770	07/28/2003	Arnold J. Levine	P1176R1C1	5778

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EXAMINER	
HOLLERAN, ANNE L	
ART UNIT	**PAPER NUMBER**
1643	

MAIL DATE	DELIVERY MODE
06/20/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/628,770	LEVINE ET AL.	
	Examiner	Art Unit	
	Anne L. Holleran	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 April 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *13-17,38,40 and 44* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13-17,38,40 and 44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The amendment filed 4/4/2007 is acknowledged. Claims 1-12, 18-37, 39 and 41-43 are canceled. Claim 44 is added.

Claims 13-17, 38, 40 and 44 are examined on the merits.

Claim Objections/Rejections Withdrawn:

Claim Objections

2. The objection to claims 13 and 15 for depending from claims that are withdrawn from consideration is withdrawn in view of the amendments to the claims.

Claim Rejections - 35 USC § 112

3. The rejection of claims 14, 16 and 17 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of the amendments to the claims.

Claim Objections/Rejections Maintained and New Grounds of Rejection:

4. Claims 14 and 44 are objected to because of the phrases "polypeptide of SEQ ID NO: 3" and "polypeptide of SEQ ID NO: 6". This should be corrected to: "polypeptide comprising the amino acid sequence of SEQ ID NO: 3" and "polypeptide comprising the amino acid sequence of SEQ ID NO: 6".

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 13-17, 38, 40 and 44 remain/are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The basis for this rejection is that the specification fails to teach one of skill in the art how to use the claimed inventions.

Claims 13-17, 38 and 40 were rejected under 35 USC 112, first paragraph for lack of an enabling disclosure, both on the basis of the breadth of the claims (some of the claims encompassed polypeptide variants) and on the basis that one of skill in the art would not know how to use the claimed polypeptides. Applicants have argued that the specification provides adequate enablement to one of skill in the art for how to use the claimed polypeptides because the specification provides the basis for using the claimed polypeptides for diagnosing Wnt-1 associated cancers.

This argument is not found persuasive because applicants have not provided any evidence that there is a classification of cancer type that may be diagnosed as Wnt-1 associated, and has also failed to provide evidence that the expression of clone 65 polypeptides or any polypeptide that is a variant encompassed by the phrase "polypeptide having at least 90% sequence identity

to the sequence of SEQ ID NO: 3 or SEQ ID NO: 6" is actually differentially expressed in a Wnt-1 associated cancer. The data provided by the specification demonstrates that in a mouse mammary cell line that has been transfected with Wnt-1 that differential expression of SEQ ID NO: 6 occurs. In contrast, as discussed in the previous Office action, Kirikoshi, when studying cancer cell lines and comparing to primary tumor samples, was unable to find a role for a clone 65 polypeptide (referred to by Kirikoshi as "WRCH1"). Applicants argue that because Kirikoshi did not limit the study to Wnt-1 associated tumors that the teachings of Kirikoshi do not undermine the claimed inventions. Applicants further point to the teachings of Kumar as clearly indicating the involvement of Wrch-1 in the regulation of cancer cells by PAK-1. A review of Kumar does not appear to provide this teaching because there does not appear to be even one mention of Wrch-1, and further even if Kumar did provide this teaching, it is not clear to the examiner that this would enable one of skill in the art to use differential expression of clone 65 proteins for the purpose of diagnosing cancer or diagnosing Wnt-1 associated cancers. While there may be an association between Wnt-1 expression and clone 65 polypeptides, the specification has only shown this association to be for two specific polypeptides, that of a polypeptide comprising the amino acid sequence of SEQ ID NO: 3 and comprising the amino acid sequence of SEQ ID NO: 6. Further, an association between the Wnt-1 expression and clone 65 expression does not provide evidence that clone 65 polypeptides may be used as diagnostic markers. The expression in primary tumors may be transient or may be limited to a certain phase of cancer progression.

Applicants have also provided a declaration by Dr. Scott, filed under 37 C.F.R., 1.132, which attests to the general level of predictability concerning the concordance of mRNA

differential expression with polypeptide differential expression. The declaration provided by Dr. Scott is insufficient to overcome the rejection of record, because the rejection provided many grounds for asserting that one of skill in the art would not know how to use the claimed polypeptides, and the assertion that differential mRNA expression was not predictably correlated with differential polypeptide expression was only one of the grounds.

The rejection of record is maintained because the amendments to the claims failed to obviate the rejection and because applicants' arguments were unpersuasive.

6. Claims 13, 16,17, and 38 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The basis for this rejection is that the specification fails to sufficiently describe the genus of polypeptides encompassed by the claims.

Applicants' arguments have been carefully considered, but fail to persuade. Applicants assert that the claims are now limited to a genus of polypeptides comprising clone 65 polypeptide having at least a 90% sequence identity to the sequence of SEQ ID NO: 3 or SEQ ID NO: 6, wherein the expression of said polypeptide is induced by Wnt-1. Applicants argue that the scope of the claims is fully supported by the specification because the genus encompassed by the claims is defined by 90% sequence identity to SEQ ID NO: 3 or SEQ ID NO: 6 and further defined by a functional limitation set forth as the claimed polypeptides are "induced by Wnt-1". This is not sufficient to overcome the rejection for lack of written description of the genus. The

"functional limitation" provided by the phrase "the expression of said polypeptide is induced by Wnt-1" is not a function or activity that is in any way correlated with a structure. Even if the proposition was accepted that " the expression of said polypeptide is induced by Wnt-1" constitutes a biological function or activity of a polypeptide, the specification has only provided two examples of such polypeptides, and these polypeptides are not representative of the genus, because the genus, as currently claimed, encompasses proteins where only a small portion of a second polypeptide has 90% sequence identity, because the claims do not indicate that the sequence identity is over the entire length of the polypeptides.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 13, 16, and 38 remain rejected under 35 U.S.C. 102(e) as being anticipated by Hillman (US 5,840,569; issued Nov. 24, 1998; effective filing date Dec. 12, 1996; cited in the IDS).

Applicants argue that the polypeptide of Hillman has only 74% sequence identity with SEQ ID NO: 3. This is not persuasive because the claims do not recite that the percent identity is over the entire length of the polypeptide. Therefore, the rejection is maintained for the reasons of record.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne Holleran, whose telephone number is (571) 272-0833. The examiner can normally be reached on Monday through Friday from 9:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached on (571) 272-0832. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Official Fax number for Group 1600 is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

Anne L. Holleran
Patent Examiner
June 8, 2007

LARRY R. HELMS, PH.D.
SUPERVISORY PATENT EXAMINER